Complete Summary

GUIDELINE TITLE

Standards of medical care in diabetes. VI. Prevention and management of diabetes complications.

BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association (ADA). Standards of medical care in diabetes. VI. Prevention and management of diabetes complications. Diabetes Care 2006 Jan;29(Suppl 1):S17-26.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Standards of medical care in diabetes. VI. Prevention and management of diabetes complications. Diabetes Care 2005 Jan;28(suppl 1):S14-21.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Complications of diabetes mellitus including:

- Cardiovascular disease (CVD)
  - Hypertension (HTN)
  - Dyslipidemia
  - Coronary heart disease (CHD)
- Nephropathy

- Retinopathy
- Neuropathy
    - Distal symmetric polyneuropathy (DPN)
    - Autonomic neuropathy
- Foot ulceration

GUIDELINE CATEGORY

Management
Prevention
Screening
Treatment

CLINICAL SPECIALTY

Cardiology
Endocrinology
Family Practice
Internal Medicine
Nephrology
Obstetrics and Gynecology
Ophthalmology
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Dietitians
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To provide recommendations for the prevention and management of diabetes complications
- To provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, treatment goals, and tools to evaluate the quality of care

TARGET POPULATION

Patients with type 1 or type 2 diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

Screening and Diagnosis

1. Blood pressure (systolic and diastolic)

2. Serum low-density lipoprotein (LDL), high-density lipoprotein (HDL), and triglyceride concentrations
3. Coronary heart disease screening:
    - Risk factor assessment
    - Stress electrocardiography (ECG)
    - Stress echocardiography
    - Perfusion imaging
4. Testing for microalbuminuria and annual serum creatinine measurement for glomerular filtration rate (GFR) estimation
5. Dilated and comprehensive eye exam
6. Screening for distal symmetric polyneuropathy and autonomic neuropathy
    - Electrophysiological testing, as needed
7. Foot examination
8. Screening for peripheral arterial disease (PAD):
    - History of claudication
    - Pedal pulses
    - Ankle-brachial index

Management/Treatment

1. Patient education
    - Lifestyle modification (e.g., diet, weight loss, physical activity, smoking cessation)
    - Foot care
2. Drug therapy
    - Angiotensin-converting enzyme (ACE) inhibitors
    - Angiotensin receptor blockers (ARBs)
    - Beta-blockers
    - Diuretics
    - Calcium channel blockers (CCBs)
        - Dihydropyridine calcium channel blockers (DCCBs)
        - Nondihydropyridine calcium channel blockers
    - Statins
    - Fibrates
    - Niacin
    - Combination drug therapy
    - Anti-platelet agents, including aspirin
3. Laser therapy to reduce the risk of vision loss
4. Referral to specialist

Monitoring

1. Renal function tests
2. Serum potassium levels
3. Glomerular filtration rate

MAJOR OUTCOMES CONSIDERED

- Cardiovascular events
- Lipid levels
- Morbidity and mortality associated with cardiovascular disease
- Progression of microalbuminuria to macroalbuminuria

- Glomerular filtration rate (GFR)
- Risk of retinopathy and vision loss
- Risk of foot ulcers or amputation
- Efficacy and cost-effectiveness of interventions

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence (i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford*)

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry
- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Recommendations have been assigned ratings of A, B, or C, depending on the quality of evidence (see "Rating Scheme for the Strength of the Evidence"). Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence. Recommendations with an "A" rating are

based on large, well-designed clinical trials or well done meta-analyses. Generally, these recommendations have the best chance of improving outcomes when applied to the population to which they are appropriate. Recommendations with lower levels of evidence may be equally important but are not as well supported.

COST ANALYSIS

A number of large randomized clinical trials have demonstrated the efficacy and cost-effectiveness of counseling in changing smoking behavior.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The recommendations were reviewed and approved October 2005 by the Professional Practice Committee and, subsequently, by the Executive Committee of the Board of Directors.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The evidence grading system for clinical practice recommendations (A through C, E) is defined at the end of the "Major Recommendations" field.

Cardiovascular Disease (CVD)

Hypertension (HTN)/Blood Pressure Control

Screening and Diagnosis

- Blood pressure should be measured at every routine diabetes visit. Patients found to have systolic blood pressure ≥130 mmHg or diastolic blood pressure ≥80 mmHg should have blood pressure confirmed on a separate day. (C)

Goals

- Patients with diabetes should be treated to a systolic blood pressure <130 mmHg. (C)
- Patients with diabetes should be treated to a diastolic blood pressure <80 mmHg. (B)

Treatment

- Patients with hypertension (systolic blood pressure ≥140 mmHg or diastolic blood pressure ≥90 mmHg) should receive drug therapy in addition to lifestyle and behavioral therapy. (A)

- Multiple drug therapy (two or more agents at proper doses) is generally required to achieve blood pressure targets. (B)
- Patients with a systolic blood pressure of 130 to 139 mmHg or a diastolic blood pressure of 80 to 89 mmHg should be given lifestyle and behavioral therapy alone for a maximum of 3 months and then, if targets are not achieved, in addition, be treated with pharmacological agents that block the renin-angiotensin system. (E)
- Initial drug therapy for those with a blood pressure >140/90 mmHg should be with a drug class demonstrated to reduce CVD events in patients with diabetes (angiotensin-converting enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs], beta-blockers, diuretics, and calcium channel blockers). (A)
- All patients with diabetes and hypertension should be treated with a regimen that includes either an ACE inhibitor or an ARB. If one class is not tolerated, the other should be substituted. If needed to achieve blood pressure targets, a thiazide diuretic should be added. (E)
- If ACE inhibitors, ARBs, or diuretics are used, monitor renal function and serum potassium levels. (E)
    - In patients with type 1 diabetes, with hypertension and any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy. (A)
    - In patients with type 2 diabetes, hypertension, and microalbuminuria, ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria. (A)
    - In those with type 2 diabetes, hypertension, macroalbuminuria, and renal insufficiency, ARBs have been shown to delay the progression of nephropathy. (A)
- In pregnant patients with diabetes and chronic hypertension, blood pressure target goals of 110 to 129/65 to 79 mmHg are suggested in the interest of long-term maternal health and minimizing impaired fetal growth. ACE inhibitors and ARBs are contraindicated during pregnancy. (E)
- In elderly hypertensive patients, blood pressure should be lowered gradually to avoid complications. (E)
- Patients not achieving target blood pressure despite multiple drug therapy should be referred to a physician experienced in the care of patients with hypertension. (E)
- Orthostatic measurement of blood pressure should be performed in people with diabetes and hypertension when clinically indicated. (E)

Dyslipidemia/Lipid Management

Screening

- In adult patients, test for lipid disorders at least annually and more often if needed to achieve goals. In adults with low-risk lipid values (low-density lipoprotein [LDL] <100 mg/dL, high-density lipoprotein [HDL] >50 mg/dL, and triglycerides <150 mg/dL), lipid assessments may be repeated every 2 years. (E)

Treatment Recommendations and Goals

- Lifestyle modification focusing on the reduction of saturated fat and cholesterol intake, weight loss (if indicated), and increased physical activity has been shown to improve the lipid profile in patients with diabetes. (A)
- In individuals without overt CVD
    - The primary goal is an LDL <100 mg/dL (2.6 mmol/L). (A)
    - For those over the age of 40 years, statin therapy to achieve an LDL reduction of 30 to 40% regardless of baseline LDL levels is recommended. (A)
    - For those under the age of 40 years but at increased risk due to other cardiovascular risk factors who do not achieve lipid goals with lifestyle modifications alone, the addition of pharmacological therapy is appropriate. (C)
- In individuals with overt CVD
    - All patients should be treated with a statin to achieve an LDL reduction of 30 to 40%. (A)
    - A lower LDL cholesterol goal of <70 mg/dL (1.8 mmol/L), using a high dose of a statin, is an option. (B)
- Lower triglycerides to <150 mg/dL (1.7 mmol/L) and raise HDL cholesterol to >40 mg/dL (1.15 mmol/L). In women, an HDL goal 10 mg/dL higher (>50 mg/dL) should be considered. (C)
- Lowering triglycerides and increasing HDL cholesterol with a fibrate is associated with a reduction in cardiovascular events in patients with clinical CVD, low HDL, and near-normal levels of LDL. (A)
- Combination therapy using statins and other lipid-lowering agents may be necessary to achieve lipid targets but has not been evaluated in outcomes studies for either CVD event reduction or safety. (E)
- Statin therapy is contraindicated in pregnancy. (E)

Anti-platelet Agents

- Use aspirin therapy (75 to 162 mg/day) as a secondary prevention strategy in those with diabetes with a history of CVD. (A)
- Use aspirin therapy (75 to 162 mg/day) as a primary prevention strategy in those with:
    - Type 2 diabetes at increased cardiovascular risk, including those who are >40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria) (A)
    - Type 1 diabetes at increased cardiovascular risk, including those who are >40 years of age or who have additional risk factors (family history of CVD, hypertension, smoking, dyslipidemia, or albuminuria) (C)
- Consider aspirin therapy in people between the age of 30 and 40 years, particularly in the presence of other cardiovascular risk factors. (E)
- Aspirin therapy should not be recommended for patients under the age of 21 years because of the increased risk of Reye's syndrome associated with aspirin use in this population. People <30 years have not been studied. (E)
- Combination therapy using other antiplatelet agents such as clopidogrel in addition to aspirin should be used in patients with severe and progressive CVD. (C)
- Other antiplatelet agents may be a reasonable alternative for high-risk patients with aspirin allergy, bleeding tendency, receiving anticoagulant

therapy, recent gastrointestinal bleeding, and clinically active hepatic disease who are not candidates for aspirin therapy. (E)

Smoking Cessation

- Advise all patients not to smoke. (A)
- Include smoking cessation counseling and other forms of treatment as a routine component of diabetes care. (B)

Coronary Heart Disease (CHD) Screening and Treatment

- In patients >55 years of age, with or without hypertension but with another cardiovascular risk factor (history of CVD, dyslipidemia, microalbuminuria, or smoking), an ACE inhibitor (if not contraindicated) should be considered to reduce the risk of cardiovascular events. (A)
- In patients with a prior myocardial infarction or in patients undergoing major surgery, beta-blockers, in addition, should be considered to reduce mortality. (A)
- In asymptomatic patients, consider a risk factor evaluation to stratify patients by 10-year risk and treat risk factors accordingly. (B)
- In patients with treated congestive heart failure (CHF), metformin use is contraindicated. The thiazolidinediones are associated with fluid retention, and their use can be complicated by the development of congestive heart failure. Caution in prescribing thiazolidinediones in the setting of known congestive heart failure or other heart diseases, as well as in patients with preexisting edema or concurrent insulin therapy, is required. (C)

Nephropathy Screening and Treatment

General Recommendations

- To reduce the risk and/or slow the progression of nephropathy, optimize glucose control. (A)
- To reduce the risk and/or slow the progression of nephropathy, optimize blood pressure control. (A)
- To reduce the risk of neuropathy, protein intake should be limited to the recommended dietary allowance (RDA) (0.8 g/kg) in those with any degree of chronic kidney disease (CKD). (B)

Screening

- Perform an annual test for the presence of microalbuminuria in type 1 diabetic patients with diabetes duration of $\geq$5 years and in all type 2 diabetic patients, starting at diagnosis and during pregnancy. (E)
- Serum creatinine should be measured at least annually for the estimation of glomerular filtration rate (GFR) in all adults with diabetes regardless of the degree of urine albumin excretion. The serum creatinine alone should not be used as a measure of kidney function but instead used to estimate glomerular filtration rate and stage the level of chronic kidney disease. (E)

Treatment

- In the treatment of both micro- and macroalbuminuria, either ACE inhibitors or ARBs should be used except during pregnancy. (A)
- While there are no adequate head-to-head comparisons of ACE inhibitors and ARBs, there is clinical trial support for each of the following statements:
    - In patients with type 1 diabetes, with hypertension and any degree of albuminuria, ACE inhibitors have been shown to delay the progression of nephropathy. (A)
    - In patients with type 2 diabetes, hypertension, and microalbuminuria, ACE inhibitors and ARBs have been shown to delay the progression to macroalbuminuria. (A)
    - In patients with type 2 diabetes, hypertension, macroalbuminuria, and renal insufficiency (serum creatinine >1.5 mg/dL), ARBs have been shown to delay the progression of nephropathy. (A)
    - If one class is not tolerated, the other should be substituted. (E)
- With presence of nephropathy, initiate protein restriction to $\leq$0.8 g/kg body wt/day (approximately 10% of daily calories), the current adult recommended dietary allowance for protein. Further restriction may be useful in slowing the decline of glomerular filtration rate in patients whose neuropathy is progressing despite maximized glycemic and blood pressure control and use of ACE inhibitors and/or ARBs. (B)
- With regards to slowing the progression of nephropathy, the use of dihydropyridine calcium channel blockers (DCCBs) as initial therapy is not more effective than placebo. Their use in nephropathy should be restricted to additional therapy to further lower blood pressure in patients already treated with ACE inhibitors or ARBs. (B)
- In the setting of albuminuria or nephropathy, in patients unable to tolerate ACE inhibitors and/or ARBs, consider the use of non-DCCBs, beta-blockers, or diuretics for the management of blood pressure. Use of non-DCCBs may reduce albuminuria in diabetic patients, including during pregnancy. (E)
- If ACE inhibitors, ARBs, or diuretics are used, monitor serum potassium levels for the development of hyperkalemia. (B)
- Continued surveillance of microalbuminuria/proteinuria to assess both response to therapy and progression of disease is recommended. (E)
- Consider referral to a physician experienced in the care of diabetic renal disease when the estimated glomerular filtration rate has fallen to <60 mL/min 1.73 m^2 or if difficulties occur in the management of hypertension or hyperkalemia. (B)

Retinopathy Screening and Treatment

General Recommendations

- Optimal glycemic control can substantially reduce the risk and progression of diabetic retinopathy. (A)
- Optimal blood pressure control can reduce the risk and progression of diabetic retinopathy. (A)
- Aspirin therapy does not prevent retinopathy or increase the risks of hemorrhage. (A)

Screening

- Adults and adolescents with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 3 to 5 years after the onset of diabetes. (B)
- Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes. (B)
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. Less frequent exams (every 2 to 3 years) may be considered in the setting of a normal eye exam. Examinations will be required more frequently if retinopathy is progressing. (B)
- Women who are planning pregnancy or who have become pregnant should have a comprehensive eye examination and should be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examinations should occur in the first trimester with close follow-up throughout pregnancy and for 1 year postpartum. This guideline does not apply to women who develop gestational diabetes mellitus (GDM) because such individuals are not at increased risk for diabetic retinopathy. (B)

Treatment

- Laser therapy can reduce the risk of vision loss in patients with high-risk characteristics (HRCs). (A)
- Promptly refer patients with any level of macular edema, severe nonproliferative diabetic retinopathy (NPDR), or any proliferative diabetic retinopathy (PDR) to an ophthalmologist who is knowledgeable and experienced in the management and treatment of diabetic retinopathy. (A)

<u>Neuropathy Screening and Treatment</u>

- All patients should be screened for distal symmetric polyneuropathy (DPN) at diagnosis and at least annually thereafter, using simple clinical tests. (A)
- Electrophysiological testing is rarely ever needed, except in situations where the clinical features are atypical. (E)
- Once the diagnosis of distal symmetric polyneuropathy is established, special foot care is appropriate for insensate feet to decrease the risk of amputation. (B)
- Simple inspection of insensate feet should be performed at 3- to 6-month intervals. An abnormality should trigger referral for special footwear, preventive specialist, or podiatric care. (B)
- Screening for autonomic neuropathy should be instituted at diagnosis of type 2 diabetes and 5 years after the diagnosis of type 1 diabetes. Special electrophysiological testing for autonomic neuropathy is rarely needed and may not affect management and outcomes. (E)
- Education of patients about self-care of the feet and referral for special shoes/inserts are vital components of patient management. (B)
- A wide variety of medications is recommended for the relief of specific symptoms related to autonomic neuropathy, as they improve the quality of life of the patient. (E)

<u>Foot Care</u>

- Perform a comprehensive foot examination and provide foot self care education annually on patients with diabetes to identify risk factors predictive of ulcers and amputations. (B)
- The foot examination can be accomplished in a primary care setting and should include the use of a monofilament, tuning fork, palpation, and a visual examination. (B)
- A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. (B)
- Refer patients who smoke or with prior lower-extremity complications to foot care specialists for ongoing preventative care and life-long surveillance. (C)
- Initial screening for peripheral arterial disease (PAD) should include a history for claudication and an assessment of the pedal pulses. Consider obtaining an ankle-brachial index (ABI), as many patients with peripheral arterial disease are asymptomatic. (C)
- Refer patients with significant claudication or a positive ankle-brachial index for further vascular assessment and consider exercise, medications, and surgical options. (C)

Definitions:

American Diabetes Association's Evidence Grading System for Clinical Practice Recommendations

A

Clear evidence from well-conducted, generalizable, randomized controlled trials that are adequately powered, including:

- Evidence from a well-conducted multicenter trial
- Evidence from a meta-analysis that incorporated quality ratings in the analysis
- Compelling non-experimental evidence (i.e., "all or none" rule developed by the Center for Evidence Based Medicine at Oxford*)

Supportive evidence from well-conducted randomized, controlled trials that are adequately powered, including:

- Evidence from a well-conducted trial at one or more institutions
- Evidence from a meta-analysis that incorporated quality ratings in the analysis

*Either all patients died before therapy and at least some survived with therapy, or some patients died without therapy and none died with therapy. Example: use of insulin in the treatment of diabetic ketoacidosis.

B

Supportive evidence from well-conducted cohort studies, including:

- Evidence from a well-conducted prospective cohort study or registry

- Evidence from a well-conducted meta-analysis of cohort studies

Supportive evidence from a well-conducted case-control study

C

Supportive evidence from poorly controlled or uncontrolled studies, including:

- Evidence from randomized clinical trials with one or more major or three or more minor methodological flaws that could invalidate the results
- Evidence from observational studies with high potential for bias (such as case series with comparison with historical controls)
- Evidence from case series or case reports

Conflicting evidence with the weight of evidence supporting the recommendation

E

Expert consensus or clinical experience

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate prevention and management of diabetes complications

POTENTIAL HARMS

- Combination therapy, with a statin and a fibrate or statin and niacin, may be efficacious for patients needing treatment for all three lipid fractions, but this combination is associated with an increased risk for abnormal transaminase levels, myositis, or rhabdomyolysis. The risk of rhabdomyolysis seems to be lower when statins are combined with fenofibrate than gemfibrozil. There is also a risk of a rise in plasma creatinine, particularly with fenofibrate. It is important to note that clinical trials with fibrates and niacin have demonstrated benefits in patients who were not on treatment with statins and that there is no data available on reduction of events with such combinations.

The risks may be greater in patients who are treated with combinations of these drugs with high doses of statins.
- The thiazolidinediones (TZDs) are associated with fluid retention, and their use can be complicated by the development of congestive heart failure (CHF). Caution in prescribing thiazolidinediones in the setting of known congestive heart failure or other heart diseases, as well as in patients with preexisting edema or concurrent insulin therapy, is required.
- Given the risk of a modest loss of visual acuity and of contraction of visual field from panretinal laser surgery, such therapy has been primarily recommended for eyes approaching or reaching high-risk characteristics.
- Although cheap and generally efficacious in the management of neuropathic pain, side effects limit the use of tricyclic drugs in many patients. Tricyclic drugs may also exacerbate some autonomic symptoms such as gastroparesis.

CONTRAINDICATIONS

CONTRAINDICATIONS

- During pregnancy treatment with angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) is contraindicated, since they are likely to cause fetal damage.
- Statin therapy is contraindicated in pregnancy.
- In patients with congestive heart failure (CHF), metformin use is contraindicated.
- Aspirin therapy should not be recommended for patients under the age of 21 years because of the increased risk of Reye's syndrome associated with aspirin use in this population.
- People with aspirin allergy, bleeding tendency, receiving anticoagulant therapy, recent gastrointestinal bleeding, and clinically active hepatic disease are not candidates for aspirin therapy.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Evidence is only one component of clinical decision-making. Clinicians care for patients, not populations; guidelines must always be interpreted with the needs of the individual patient in mind. Individual circumstances, such as comorbid and coexisting diseases, age, education, disability, and, above all, patient's values and preferences, must also be considered and may lead to different treatment targets and strategies. Also, conventional evidence hierarchies, such as the one adapted by American Diabetes Association, may miss some nuances that are important in diabetes care.
- While individual preferences, comorbidities, and other patient factors may require modification of goals, targets that are desirable for most patients with diabetes are provided. These standards are not intended to preclude more extensive evaluation and management of the patient by other specialists as needed.
- When identified, the optimal therapeutic approach to the diabetic patient with silent myocardial ischemia is unknown. Certainly if major coronary artery disease (CAD) is identified, aggressive intervention appears warranted. If

minor stenoses are detected, however, whether there is any benefit to further invasive evaluation and/or therapy is unknown. There are no well-conducted prospective trials with adequate control groups to shed light on this question. Accordingly, there are no evidence-based guidelines for screening the asymptomatic diabetic patient for coronary artery disease.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

In recent years, numerous health care organizations, ranging from large health care systems such as the U.S. Veteran's Administration to small private practices have implemented strategies to improve diabetes care. Successful programs have published results showing improvement in important outcomes such as A1C measurements and blood pressure and lipid determinations as well as process measures such as provision of eye exams. Successful interventions have been focused at the level of health care professionals, delivery systems, and patients. Features of successful programs reported in the literature include:

- Improving health care professional education regarding the standards of care through formal and informal education programs.
- Delivery of diabetes self-management education (DSME), which has been shown to increase adherence to standard of care.
- Adoption of practice guidelines, with participation of health care professionals in the process. Guidelines should be readily accessible at the point of service, such as on patient charts, in examining rooms, in "wallet or pocket cards," on personal digital assistants (PDAs), or on office computer systems. Guidelines should begin with a summary of their major recommendations instructing health care professionals what to do and how to do it.
- Use of checklists that mirror guidelines have been successful at improving adherence to standards of care.
- System changes, such as provision of automated reminders to health care professionals and patients, reporting of process and outcome data to providers, and especially identification of patients at risk because of failure to achieve target values or a lack of reported values.
- Quality improvement programs combining continuous quality improvement or other cycles of analysis and intervention with provider performance data.
- Practice changes, such as clustering of dedicated diabetes visits into specific times within a primary care practice schedule and/or visits with multiple health care professionals on a single day and group visits.
- Tracking systems either with an electronic medical record or patient registry have been helpful at increasing adherence to standards of care by prospectively identifying those requiring assessments and/or treatment modifications. They likely could have greater efficacy if they suggested specific therapeutic interventions to be considered for a particular patient at a particular point in time.
- A variety of non-automated systems, such as mailing reminders to patients, chart stickers, and flow sheets, have been useful to prompt both providers and patients.
- Availability of case or (preferably) care management services, usually by a nurse. Nurses, pharmacists, and other non-physician health care professionals using detailed algorithms working under the supervision of physicians and/or

nurse education calls have also been helpful. Similarly dietitians using medical nutrition therapy (MNT) guidelines have been demonstrated to improve glycemic control.
- Availability and involvement of expert consultants, such as endocrinologists and diabetes educators.

Evidence suggests that these individual initiatives work best when provided as components of a multifactorial intervention. Therefore, it is difficult to assess the contribution of each component; however, it is clear that optimal diabetes management requires an organized, systematic approach and involvement of a coordinated team of health care professionals.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Diabetes Association (ADA). Standards of medical care in diabetes. VI. Prevention and management of diabetes complications. Diabetes Care 2006 Jan;29(Suppl 1):S17-26.

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 Nov (revised 2006 Jan)

GUIDELINE DEVELOPER(S)

American Diabetes Association - Professional Association

SOURCE(S) OF FUNDING

The American Diabetes Association received an educational grant from LifeScan, Inc., a Johnson and Johnson Company, to support publication of the 2006 Diabetes Care Supplement.

GUIDELINE COMMITTEE

Professional Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Standards of medical care in diabetes. VI. Prevention and management of diabetes complications. Diabetes Care 2005 Jan;28(suppl 1):S14-21.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Introduction. Diabetes Care 29:S1-S2, 2006
- Strategies for improving diabetes care. Diabetes Care 29:S34-S35, 2006.

Electronic copies: Available from the American Diabetes Association (ADA) Web site.

The following is also available:

- 2006 clinical practice recommendations standards of care. Personal digital assistant (PDA) download. Available from the American Diabetes Association (ADA) Web site.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 1, 1998. The information was verified by the guideline developer on December 15, 1998. It was updated by ECRI on April 1, 2000, April 2, 2001, March 14, 2002, July 29, 2003, May 26, 2004, July 1, 2005, and March 17, 2006.

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DISCLAIMER

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Readers with questions regarding guideline content are directed to contact the guideline developer.

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